Allowed Claims

As amended during interview with Examiner on May 15, 2006 (see claim 1, 18 and 23)

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1. A method for determining an analyte in a sample using an analytical element, the method comprising:

providing a mixture by contacting the sample with a binding partner 2 of a specific binding pair 1 (partner 2 of pair 1), and a binding partner 2 of a specific binding pair 2 (partner 2 of pair 2), wherein partner 2 of pair 1 and partner 2 of pair 2 **are not the analyte and** bind the analyte when the analyte is present in the sample**, wherein the mixture is provided before the mixture is added to the element**;

adding the mixture to a sample application zone of the analytical element, wherein the element comprises a material enabling liquid transport between the sample application zone and a detection zone located downstream thereof, wherein the partner 2 of pair 1 and the partner 2 of pair 2 are not immobilized on the material, wherein the detection zone comprises a binding partner 1 of specific binding pair 1 (partner 1 of pair 1) immobilized in such a manner that it is able to bind to the partner 2 of pair 1, and wherein a labeled partner 1 of specific binding pair 2 (partner 1 of pair 2) is present upstream of the detection zone and impregnated on the material such that it can be detached by liquid and is able to bind to the partner 2 of pair 2 forming, when the analyte is present in the sample, a complex comprising the partner 1 of pair 1, the partner 2 of pair 1, the analyte, the partner 1 of pair 2 and the partner 2 of pair 2, and

detecting the presence or absence of the label in the detection zone, thereby determining the analyte in the sample.

2. The method of claim 1 wherein the specific binding pair 1 and the specific binding pair 2 independently comprise a pair of specific binding partners selected from the group consisting of a hapten and an antibody, an antigen and an antibody, a lectin and a sugar/saccharide, a ligand and a receptor, avidin/streptavidin and biotin, a nucleic acid and a nucleic acid.

3. The method of claim 1 wherein the partner 1 of pair 2 is an antibody against the partner 2 of pair 2.

4. The method of claim 3 wherein the partner 1 of pair 2 is an antibody against digoxigenin or digoxin.

5. The method of claim 1 wherein the partner 1 of pair 2 is labeled with an enzyme or direct label.

6. The method of claim 5 wherein metal or latex particles are used as the direct label.

7. The method of claim 1 wherein the partner 1 of pair 2 is located in the sample application zone.

8. The method of claim 5 wherein the partner 1 of pair 2 is located in the sample application zone.

9. The method of claim 1 wherein an antibody for specific binding with an antigen or hapten is conjugated with the partner 2 of pair 1 and the antibody is conjugated with the partner 2 of pair 2.

10. The method of claim 1 wherein an antigen, hapten or oligopeptide is conjugated with the partner 2 of pair 1 and the antigen, hapten or oligopeptide is conjugated with the partner 2 of pair 2, wherein the antigen, hapten or oligopeptide specifically binds to an antibody.

11. The method of claim 1 wherein the partner 2 of pair 1 and the partner 2 of pair 2 are in separate containers prior to providing the mixture, wherein the separate containers do not include the analytical element.

12. The method of claim 1 wherein the partner 2 of pair 1 and the partner 2 of pair 2 are stored together in one container prior to providing the mixture, wherein the container does not include the analytical element.

13. The method of claim 1 wherein the partner 2 of pair 1 is conjugated to a nucleotide, oligonucleotide, a nucleic acid, an antibody, a hapten or antigen or an epitope representing an antigen or a lectin or a receptor for a ligand.

14. The method of claim 13 wherein the partner 2 of pair 1 is biotin.

15. The method of claim 1 wherein the partner 2 of pair 2 is conjugated to a nucleotide, oligonucleotide, a nucleic acid, an antibody, a hapten or antigen or an epitope representing an antigen or a lectin or a receptor for a ligand.

16. The method of claim 15 wherein the partner 2 of pair 2 is a hapten.

17. The method of claim 16 wherein wherein the hapten is digoxigenin or digoxin.

18. A method for determining the presence of an analyte using an analytical element comprising a material enabling liquid transport between a sample application zone and a detection zone located downstream thereof, wherein the detection zone comprises a binding partner 1 of specific binding pair 1 (partner 1 of pair 1) immobilized in such a manner that it is able to bind to a binding partner 2 of specific binding pair 1 (partner 2 of pair 1), and wherein a labeled partner 1 of specific binding pair 2 (partner 1 of pair 2) is present upstream of the detection zone and impregnated on the material such that it can be detached by liquid and is able to bind to a specific binding partner 2 of specific binding pair 2 (partner 2 of pair 2); the method comprising:

adding to the element at the sample application zone a substance derived from and representing the analyte wherein the substance comprises partner 2 of pair 1 and partner 2 of

pair 2 bound to the analyte, wherein partner 2 of pair 1 and partner 2 of pair 2 **are not the analyte and** are not present on the element prior to the addition of the substance to the element and wherein the substance is formed before it is added to the element,

moving the substance by liquid transport in the analytical element towards the detection zone wherein the partner 2 of pair 2 binds the partner 1 of pair 2; and

binding the substance to partner 1 of pair 1 in the detection zone; and

detecting the labelled partner 1 of pair 2 bound in the detection zone, thereby determining the presence of the analyte.

19. The method of claim 18 wherein the substance derived from and representing the analyte is formed by adding to the analyte an antibody wherein part of the antibody comprises partner 2 of pair 1 and the other part of the antibody comprises partner 2 of pair 2.

20. The method of claim 18 wherein the substance derived from and representing the analyte is formed by adding to the analyte an antigen, hapten or oligopeptide wherein a part of the antigen, hapten or oligopeptide comprises partner 2 of pair 1 and the other part of the antigen, hapten or oligopeptide comprises partner 2 of pair 2.

21. The method of claim 18 wherein the analyte is a nucleic acid which is amplified, whereby partner 2 of pair 1 or partner 2 of pair 2 is bound to a nucleotide or to an oligonucleotide that is incorporated into the amplification product of said nucleic acid, and the amplification product is hybridized with a complementary nucleic acid having partner 2 of pair 1

or partner 2 of pair 2 bound thereto, provided that when the amplification product has partner 2 of pair 1 bound thereto, the complementary nucleic acid has partner 2 of pair 2 bound thereto and when the amplification product has partner 2 of pair 2 bound thereto, the complementary nucleic acid has partner 2 of pair 1 bound thereto.

22. The method of claim 18 wherein the analyte is a nucleic acid and said substance comprises the nucleic acid hybridized with two nucleic acid probes one of which contains partner 2 or pair 1 and the other contains partner 2 of pair 2.

23. (Cancelledl) ~~An analytical element for determining the presence of an analyte, the element consisting essentially of a material enabling liquid transport between a sample application zone where a sample is applied and a detection zone located downstream thereof, wherein the detection zone contains a partner 1 of a specific binding pair 1 (partner 1 of pair 1) immobilized in such a manner that it is able to bind to a partner 2 of the specific binding pair 1 (partner 2 of pair 1) when the partner 2 of pair 1 contacts the partner 1 of pair 1, wherein the partner 2 of pair 1 is not the analyte, and wherein a labeled partner 1 of a specific binding pair 2 (partner 1 of pair 2) is present upstream of the detection zone and impregnated on a material such that it can be detached by liquid and is able to bind to a partner 2 of the specific binding pair 2 (partner 2 of pair 2) when the partner 2 of pair 2 contacts the partner 1 of pair 2, and the partner 2 of pair 2 is not the analyte, wherein both the partner 2 of pair 1 and the partner 2 of pair 2 are (i) not impregnated or immobilized on the material and (ii) added to the sample to bind the analyte before the sample is applied to the application zone.~~